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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,781	09/12/2003	Richard David Guarino	P-5769	5859

32330 7590 09/02/2005

DAVID W. HIGHET, VICE PRESIDENT  
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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/660,781	GUARINO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 14-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/26/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1, 2, 13-16 and 5-12 (as depending on claim 1) and applicants' election of a single CAR species such as hyaluronic acid in the reply filed on 7/15/2005 is acknowledged.

Claims 3, 4 and 17-43 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups of inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 7/15/2005.

Claims 1, 2, 5-12 (as depending on claim 1) and 13-16 are under examination in the instant office action.

### ***Claim Objections***

Claims 1, 2, 5-12 and 13-16 are objected to because of the following informalities:

Claims 1 and 2 recite the presence of an "optional" third component (ECM protein) in addition to CAR (component 1) and collagen VI (component 2). The elected invention is drawn to the use of a 2-component coating material. Appropriate correction is required. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Rejections - 35 USC § 112***

Claims 1, 2, 5-12 and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1 is rendered indefinite by reciting “a biologically active fragment or variant” of collagen VI. The as-filed specification definitions of the meaning of the term “biologically active” relates to activity in promoting cell attachment, survival and/or proliferation (page 2, lines 11-12). However, these definitions are unreasonably broad and fail to point out any specific sequences and/or structures of collagen type VI as intended for promoting cell attachment, survival and/or proliferation. There are several types of collagens and the collagens are well known substrates for cell attachment, cell culturing and cell proliferation. Thus, the concept of “a biologically active fragment or variant” of collagen VI that would promote cell attachment, survival and/or proliferation clearly overlaps with either whole or fragment or variant of any other collagen type. Thus, the claimed meaning of using fragment or variant of collagen VI is uncertain and indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1 and 5-16 rejected under 35 U.S.C. 102(b) as being anticipated by McDevitt et al. (“Interaction of intact type VI collagen with hyaluronan”. Febs letters, (1991), Vol. 294, No. 3, pages 167-170).

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Claims are directed to a surface comprising a support coated with 2 materials that are a cell adhesion resistant (CAR) material (component 1) and collagen VI (component 2) that is bound to the CAR material. The CAR material is hyaluronic acid (HA). Some claims are further drawn to a support made from polymers including polystyrene. Some claims are further drawn to an article of manufacture intended as well, plate or medical device that comprises the claimed coated surface.

McDevitt et al. discloses micro-wells coated with hyaluronan and type VI collagen (see abstract, for example). The well are made from polystyrene (page 168, par. 5). The coated micro-well is intended for medical research. Thus, the cited reference anticipates the claimed invention because it teaches identical article with identical surface coated with 2 identical materials as required by the presently claimed invention of the elected Group I.

2. Claims 1, 2, 5-12 and 13-16 are rejected under 35 U.S.C. 102(a, e) as being anticipated by US 2003/0113812 (Hemperly).

Claims are directed to a surface comprising a support coated with a cell adhesion resistant (CAR) material and collagen VI that is bound to the CAR material. The CAR material is hyaluronic acid (HA). Some claims are further drawn to a support made from various natural or synthetic generic polymer or composite including polystyrene. Some claims are further drawn to an article of manufacture intended as well, plate or medical device that comprises the claimed coated surface.

US 2003/0113812 disclose a surface comprising a support coated with a cell adhesion resistant (CAR) material including HA and collagen VI that is bound to the CAR material

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(example 1, see par. 0112 and table 1). The support is made from various natural or synthetic generic polymer or composite including polystyrene (see par. 0071). The coated surface is used for attaching and/or culturing cells in various medical devices (par. 0071). The cited US 2003/0113812 also teaches that use of various EM proteins and polycationic polymers (table 1, par. 0060). Thus, the cited patent anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 2, 5-12 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0113813 (Heidaran et al.).

Claims are directed to a surface comprising a support coated with a cell adhesion resistant (CAR) material and collagen VI that is bound to the CAR material. The CAR material is hyaluronic acid (HA). Some claims are further drawn to a support made from various natural or synthetic generic polymer or composite including polystyrene. Some claims are further drawn to an article of manufacture intended as well, plate or medical device that comprises the claimed coated surface.

US 2003/0113813 (Heidaran et al.) discloses an article of manufacture or medical device(s) with surfaces coated with CAR such as HA and collagen (for example: see abstract and Fig. 1a; see par. 0236 through 0245). In particular embodiment the collagens are types I, II, IV

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and V (par. 0245). The cited patent suggests the use of collagen type VI (see col. 22, claim 32).

The surface support is made from various natural or synthetic generic polymer or composite including polystyrene. Optional materials are various EM proteins and polycationic polymers (par. 0237 and par. 0244, for example).

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary. It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use various types of collagen with a reasonable expectation of success in obtaining devices suitable for culturing cells as clearly suggested by the cited patent.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

2. Claims 1, 2, 5-12 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDevitt et al. ("Interaction of intact type VI collagen with hyaluronan". Febs letters, (1991), Vol. 294, No. 3, pages 167-170) taken with Aumailley et al. (IDS reference; Experimental Cell research. 1989, 81:463-474), US 6,129,956 (Morra et al.) and Drumheller et al. (IDS reference ; In:"Interfacial Phenomena and Bioproducts". 1996; chapter 11, pages 273-310).

Aumailley et al. discloses a cell culture surface coated with collagen VI and teaches that various fibroblasts cell lines and tumor cells are able to attach and spread on substrates of collagen VI substrate and/or fragments thereof (abstract) with various degree (table 1). The

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reference teaches that cell support system is a plastic dish and, thus, the reference is lacking disclosure about HA coating.

However, US 6,129,956 (Morra et al.) teaches surface coated with HA in the field of surgery and diagnostics research (abstract) including cell culturing and cell attachment research (example 5). The cited patent teaches that devices made from polymeric materials including polystyrene (col. 10, lines 2 or line 47) and coated with HA and polycationic substances including PIE, polylysine, etc (col. 8, lines 65-67; col. 10, lines 45-67) inhibit adhesion of bacteria present in biological fluids (abstract; col. 9, lines 47-49; example 5). US 6,129,956 (Morra et al.) also teaches that HA surface can be further treated and/or reacted with functional groups of various molecules including proteins (col.7, line 53).

McDevitt et al. demonstrates micro-wells coated with hyaluronan and type VI collagen (see abstract, for example) that is used in the field medical diagnostics and research.

The cited reference Drumheller et al. teaches concepts of designing surfaces coated with bioactive peptides including patterned substrates comprising combination of nonadhesive and adhering coating materials (page 290) to achieve more direct control over cellular interactions with surfaces and to study for mechanism of protein adhesion and cellular morphology.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine non-adhesive and adhesive coating materials including HA and collagen IV respectively with a reasonable expectation of success in obtaining a cell support surface that allows for direct control over cellular interactions with surfaces as taught by Drumheller et al. It is know that various cells have various degree of attachment with collagen VI substrate and that HA substrate is non-adhesive as adequately demonstrated by



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Aumailley et al. and US 6,129,956 (Morra et al.). One of skill in the art would have been motivated to design patterned surfaces to achieve more direct control over cellular interactions with surfaces and to reduce number of complicating factors involved as taught by Drumheller et al. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 2, 5-12 and 13-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/260,737 (Heidaran et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to a surface coated with a CAR material including HA and a bioactive agent including collagen as intended for evaluation of cell attachment and cell culturing. The co-pending claims of

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10/260,737 are broader than the instant claims and they encompass the use collagen type VI in the light of as-filed specification (original claim 32).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1, 2, 5-12 and 13-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51-61 of copending Application No. 10/259,815 (Hemperly). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to a surface coated with a CAR material including HA and a bioactive material including Collagen VI as intended for evaluation of cell attachment and cell culturing. Some co-pending claims are broader and they encompass the use of ECM proteins and synthetic polymers. However some claims of the instant application encompass the use same or similar ECM proteins and synthetic polymers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

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The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

August 30, 2005

A handwritten signature in black ink, appearing to read "V. Afremova", with a long horizontal flourish extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER